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C. 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
(in Accordance with SMDA of 1990)

Aesculap T-Bar Aneurysm Clips
October 2004

COMPANY: Aesculap[®], Inc.
3773 Corporate Parkway
Center Valley, PA 18034
Establishment Registration Number: 2916714

CONTACT: Matthew M. Hull
800-258-1946 x 5072 (phone)
610-791-6882 (fax)

TRADE NAME: Aesculap T-Bar Aneurysm Clips

COMMON NAME: Aneurysm Clips

DEVICE CLASS: Class II

PRODUCT CODE: 84 HCH

CLASSIFICATION: 882.5200 – Clip, Aneurysm

REVIEW PANEL: Neurology

INDICATIONS FOR USE

The Aesculap T-Bar Aneurysm Clips are intended for occlusion of cerebral aneurysms in either a temporary or permanent manner.

DEVICE DESCRIPTION

The Aesculap T-Bar Aneurysm Clips are designed for temporary or permanent occlusion of vessels during neurosurgical procedures. They are made from either Phynox (cobalt alloy) per ISO 5832/7 or Titanium Alloy per ISO 5832/3. The clips are a fenestrated design with the jaws at 90 and 45 degree angles. They are applied with previously cleared Aesculap aneurysm clip appliers.

PERFORMANCE DATA

All required testing per "Draft Guidance for the Preparation of Premarket Notifications (510(k)s)" was completed for Aesculap T-Bar Aneurysm Clips. Biomechanical testing results demonstrate the Aesculap T-Bar Aneurysm Clips are substantially equivalent to our current aneurysm clips currently on the market.

SUBSTANTIAL EQUIVALENCE

Aesculap[®], Inc. believes that the Aesculap T-Bar Aneurysm Clips are substantially equivalent to our currently marketed Aneurysm Clips.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 9 2004

Mr. Matthew M. Hull, RAC
Regulatory Affairs Manager
Aesculap, Inc.
3773 Corporate Parkway
Center Valley, Pennsylvania 18034

Re: K043041

Trade/Device Name: Aesculap T-Bar Aneurysm Clips
Regulation Number: 21 CFR 882.5200
Regulation Name: Aneurysm Clip
Regulatory Class: II
Product Code: HCH
Dated: November 1, 2004
Received: November 9, 2004

Dear Mr. Hull:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

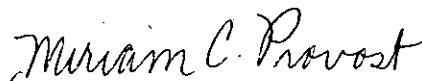
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

for 
Celia M. Witten, Ph.D., M.D.

Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

B. INDICATIONS FOR USE STATEMENT**510(k) Number:** K043041**Device Name:** Aesculap T-Bar Aneurysm Clips**Indication for Use:**

The Aesculap T-Bar Aneurysm Clips are intended for occlusion of cerebral aneurysms in either a temporary or permanent manner.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

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